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09/415,890	10/08/1999	BORJE S. ANDERSSON	UTXC:528--1	5425

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/415,890
Filing Date: October 08, 1999
Appellant(s): ANDERSSON, BORJE S.

DAVID PARKER
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/27/04 appealing from the Office action mailed 09/20/04.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 97, 99, 116, 117, 119, and 133.

Claims 121, 122, 141 and 150 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 98, no longer pending, has been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed or Appeal

The following ground(s) of rejection are applicable to the appealed claims:

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Withdrawn Rejections

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection over STEHLE-GB145732 and double obvious patenting rejections over Anderson, 10/294,491 and 10/439,252.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

6,406,713	JANOFF	06-2002
5,277,914	SZOKA	01-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 97, 99, 116, 117, 119 are rejected under 35 U.S.C. 102(e) as being anticipated by Janoff et al 6406713.

The instant invention is claimed in open language, as a method of preparing a solvent vehicle; generic-claim 97: the method steps are:

(a) obtaining a pharmaceutically acceptable dipolar aprotic solvent and/or acid;

(b) mixing the solvent and/or acid in a acceptable aqueous secondary solvent;

(c) removing more than 50% of the solvent and/or acid and secondary and solvent;

(d) reconstituting the solvent

Janoff is directed at (summary) substantially liposome free formulations for Administration of polyene antibiotics parenterally, requiring obtaining (instant 97(a) a solvent, (col.4, lines 48-50) DMSO, for the polyene antibiotics Amphotericin B or (col.9, lines 36-39) Pimaricin, Candicidin, Filipin or Nystatin. Instant step (b) requires mixing with another solvent, aqueous-Janoff proceeds (lines 56-57) col.4) to add the aqueous solution to the solvent-drug phase; then evaporate (line58, col.4) off solvent (the instant step c, removing over 50% solvent). Finally (lines 61-64, col.4) as in instant step (d) reconstituting by addition of aqueous solvent is performed. The solvent, carriers, diluents are pharmaceutically acceptable (lines 35-37). Thus the steps of obtaining solvent, mixing with secondary solvent, removing solvent, and reconstituting solvent are shown by Janoff.

Secondary considerations of the particular solvents and secondary solvents and aqueous and lipid components of the instant pharmaceutically acceptable vehicles for parenteral administration of anti fungal polyene antibiotics are also detailed by Janoff, and meet the instant dependent claims. Instant 99 first mixes pimaricin in a dipolar aprotic solvent-Janoff puts one of 5 polyene antibiotics (col.9, lines 37-39) including pimaricin, in solvents, DMSO. Claims 116, 117 require an aqueous lipid emulsion-The process as shown by Janoff of adding aqueous solutions to the lipid-drug vehicle at col.4, lines 49-57, or at claim 1, would provide an emulsion. At col.8, last paragraph, a

soy bean lipid, phosphatidyl choline, is taught as a suitable lipid, thus meeting instant claim 119. The diluents, carriers, vehicles, and solvents are pharmaceutically acceptable-chosen for biocompatibility, and low toxicity (col.10, lines 10-26) inclusive of DMSO, water, saline, and buffers for injection. Although Janoff's disclosure is directed to preparation of lipid-drug complexes for injection, a number of statements show one is to use the preparations by adding them to aqueous vehicles for pharmaceutical parenteral administration-an example is at column 6, lines 52-54-"such formulations-are stable in aqueous solutions, such as saline:" col.10, lines 19-26 – "In the hydration step-USP water for injection-;" col.12, lines 39-42- "the preparation may be lyophilized – and rehydrated in aqueous solution –".

Claims 97, 99, 116, 117, 119, 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff et al 6406713 in view of Szoka, 5277914.

Janoff teaches the instant invention, but uses solvents such as DMSO (col.4, lines 49-50). Szoka discloses such solvents to include the instantly claimed DMF (col.4, line 50, col.5, lines 8-13), also used with co-solvents and the Janoff/instant antibiotics: amphotericin, pimaricin (col.3, bottom).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, desiring to prepare stable hydrophobic antibiotic solvent vehicles, to prepare one of Janoff. The particular solvent is seen as one within the purview of the artisan to select, as equivalents taught by Szoka.

(10) Response to Argument

Appellants' traverse of Janoff as not a prima facie anticipation is not supported. Appellant states there is no aqueous solvents until after evaporation, however; (1) an alternative adds water first, and (2) the language is in comprising guise, thus the added elements of Janoff, including the additional solvents for drugs, are permitted; appellant, too, adds steps- the insertion of the polyene antibiotic/antifungal pimaricin at claim 99. Janoff's homgenization of lipid and water is seen as providing an emulsion of the lipid/water mix- whether or not Janofff labels it emulsion. The Janoff preparation of the lipid-drug complexes free of liposomes (claim 1 of Janoff) thus meets the instant invention of obtaining a solvent, mixing with a secondary solvent, removing the solvent, and reconstituting with water, saline buffer, to provide stable injectable formulations (col.6, lines 52-54).

Appellants arguments re Szoka are that no prima facie obviousness is shown, however both references show a variety of solvents, and Janoff states that the solvent is chosen as to maximize solution of the particular drug, provide biocompatability and reduce toxicity and flammobility (col.10, lines 10-13). Szokas' expanded list of solvents is shown to include Janoff's DMSO and alcohols, and DMA (col.4, lines 46-61). Szoka utilizes these solvents with lipid particles and the instant polyene antibiotics, pimaricin and amphotericin B (col.3, line 65, 66), of Janofff and the instant invention, thus obvious to substitute if desired with equivalent available solvents having bio compatibility, drug solvation, low toxicity and/or low flammability.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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